510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

510(k) Number: K041898

Purpose for Submission: Notification of intent to manufacture and market the device: Liquid TDM Controls (Three Levels)

Analyte: TDM – Acetaminophen, Amikacin, Carbamazepine, Digoxin, Disopyramide, Ethosuximide, Gentamicin, Lidocaine, Lithium, N-Acetylprocainamide, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid, and Vancomycin.
Calibration Verifiers – Acetaminophen, Amikacin, Caffeine, Carbamazepine, Digoxin, Disopyramide, Gentamicin, Lidocaine, Lithium, N-Acetylprocainamide, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Theophylline, Tobramycin, Valproic Acid, and Vancomycin.

A. Type of Test: n/a

B. Applicant: Cliniqa Corporation

C. Proprietary and Established Names: Proprietary - Cliniqa Liquid QC^{tm} TDM Controls Level 1, 2, &3 – Cliniqa LiniCAL^{tm} TDM Calibration Verifiers Levels A – E for Olympus Systems^{tm} **Established –** Quality Control Material

Regulatory Information:

1. Regulation section: 21 CFR 862.1660

2. Classification: Class I

3. Product Code: JJX

4. Panel: 75

D. Intended Use:

1. Intended use(s): **Cliniqa Liquid QC^{tm} TDM Controls Level 1, 2, & 3** are intended for use as an assayed quality control material. Three assayed levels of Acetaminophen, Amikacin, Carbamazepine, Digoxin, Disopyramide, Ethosuximide, Gentamicin, Lidocaine, Lithium, N-Acetylprocainamide, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid, and Vancomycin are provided.

Cliniqa LiniCAL^{tm} TDM Calibration Verifiers Levels A – E for Olympus AU Systems^{tm} are assayed, liquid, quality control products which may be used to

evaluate the performance of the Olympus AU Systems[tm] for Acetaminophen, Amikacin, Caffeine, Carbamazepine, Digoxin, Disopyramide, Gentamicin, Lidocaine, Lithium, N-Acetylprocainamide, Phenobarbital, Phenytoin, primidone, Procainamide, Quinidine, Theophylline, Tobramycin, Valproic Acid, and Vancomycin at five useful concentrations.

2. Indication(s) for use: These products can aid clinical laboratory personnel to objectively monitor the accuracy and precision of clinical methods.

3. Special condition for use statement(s): For prescription use only

4. Special instrument Requirements: Cliniqa LiniCAL[tm] TDM Calibration Verifiers Levels A – E for Olympus AU Systems[tm] are designed for use on the Olympus AU Systems[tm].

E. Device Description: Quality Control Material (Assayed)

Substantial Equivalence Information:

1. Predicate device name(s): Cliniqa Liquid QC[tm] TDM Controls Level 1, 2, & 3 are substantially equivalent to MAS PAR Brand TDM Liquid Assayed Therapeutic Drug Monitoring Controls Levels 1, 2, & 3. Cliniqa LiniCAL[tm] TDM Calibration Verifiers Levels A – E for Olympus AU Systems[tm] are substantially equivalent to LiniCAL[tm] Clinical Chemistry Verifiers Levels A – E for the Beckman Coulter Synchron Systems.

2. Predicate K number(s): MAS PAR Brand TDM Liquid Assayed Therapeutic Drug Monitoring Controls Levels 1, 2, & 3– k032826 & LiniCAL[tm] TDM Calibration Verifiers Levels A – E for Olympus AU Systems[tm] - k031921.

3. Comparison with predicate:

Cliniqa Liquid QC[tm] TDM Controls Level 1, 2, & 3		
Item	**Device**	**Predicate**
Intended Use	Assayed quality control material	Assayed quality control material
Matrix	Serum based liquid	Serum based liquid
Constituents	Acetaminophen, Amikacin, Carbamazepine, Digoxin, Disopyramide, Ethosuximide, Gentamicin, Lidocaine, Lithium, N-Acetylprocainamide, Phenobarbital, Phenytoin,	Acetaminophen, Amikacin, Amitriptyline, Caffeine, Carbamazepine, Chloramphenicol, Cocaine, Cyclosporine, Desipramine, Digoxin,

Cliniqa Liquid QC™ TDM Controls Level 1, 2, & 3		
Item	**Device**	**Predicate**
	Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid, and Vancomycin	Disopyramide, Estriol, Ethanol, Ethosuximide, Gentamicin, Imipramine, Lidocaine, Lithium, Methotrexate, N-Acetylprocainamide, Netilmicin, Nortriptyline, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Total T3-Triidothyronine, Total T4, Tricyclic Antidepressants, TSH, Valporic Acid, and Vancomycin.
		Assigned values differ
Target range	Assigned values differ	

Cliniqa LiniCAL™ TDM Calibration Verifiers Levels A – E for Olympus AU Systems™		
Item	**Device**	**Predicate**
Intended Use	Assayed quality control material	Assayed quality control material
Matrix	Serum based liquid	Serum based liquid
Constituents	Acetaminophen, Amikacin, Carbamazepine, Digoxin, Disopyramide, Ethosuximide, Gentamicin, Lidocaine, Lithium, N-Acetylprocainamide, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin,	Albumin, BUN, calcium, creatinine, lactate, magnesium, phosphorus, total protein, triglycerides, glucose, iron, sodium, potassium, chloride.

Cliniqa LiniCAL™ TDM Calibration Verifiers Levels A – E for Olympus AU Systems™		
Item	**Device**	**Predicate**
	Valproic Acid, and Vancomycin	

F. Standard/Guidance Document Referenced (if applicable): Arrhenius model of accelerated elevated temperature studies.

G. Test Principle: N/A

Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility: N/A

    b. Linearity/assay reportable range: N/A

    c. Traceability (controls, calibrators, or method): "Expected Values" presented in each lot-specific insert of CLINIQA Liquid QC TDM Controls Levels 1, 2 & 3 will be generated on the Roche Integra and the Olympus AU Systems. Expected values presented in each lot-specific insert of LiniCAL TDM Calibration Verifiers Levels A – E will be generated on the Olympus AU Systems. Data points will be obtained from replicate assays obtained by multiple laboratories. A minimum of 12 data points will be used to determine the mean. Within and between assay Standard Deviations and Coefficient of Variations will be calculated for each set of data. Stability characteristics of the CLINIQA Liquid QC TDM Controls Levels 1, 2 & 3 and the of LiniCAL TDM Calibration Verifiers Levels A – E were determined using the Arrhenius model of accelerated elevated temperature studies to predict estimated storage stability at 2 – 8 ^{o}C. Open vial stability was determined in a real time on board stability study at 2-8 ºC on an Olympus AU 400 chemistry analyzer.

    d. Detection limit: N/A

    e. Analytical specificity: N/A

    f. Assay cut-off: N/A

2. Comparison studies:
    a. Method comparison with predicate device: N/A

b. Matrix comparison: N/A

3. Clinical studies:
   a. Clinical sensitivity: N/A

   b. Clinical specificity: N/A

   c. Other clinical supportive data (when a and b are not applicable): N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

H. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.